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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/339,352	06/23/99	REED-GITOMER	B UTSD: 553

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EXAMINER

ROBINSON, H

ART UNIT	PAPER NUMBER
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1653

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DATE MAILED: 04/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/339,352

Applicant(s)

Reed-Gitomer et al.

Examiner

Hope Robinson

Group Art Unit

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☒ Responsive to communication(s) filed on Jan 27, 1900

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8, 10-15, and 17 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8, 10-15, and 17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicant's response to the Office Action mailed October 21, 1999 in Paper No. 6 on January 27, 1999 is acknowledged.
2. Applicant's cancellation of Claims 9,16 and 18-26 is acknowledged.
3. Claims 1 and 12 have been amended. Rejections under 35 U.S.C. 112 first paragraph and second paragraph have been withdrawn.
4. The following grounds of rejection are or remain applicable:

Priority

5. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) as follows:

The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuing

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application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971).

The examiner read the provisional application and did not find support for sequences recited in the claims and disclosed in the specification (SEQ ID No. 1 which encodes the protein contained in SEQ ID No.2) of the current application. Furthermore, the provisional application did not disclose the marker D1S2681 wherein the genomic region of the invention is comprised. Therefore, this application will not get the Priority date of the provisional application in regard to the present claims but only the filing date of the present application which is June 23, 1999.

6. Applicant's arguments filed on January 27, 2000 in Paper No. 6 have been fully considered but they are not persuasive. The response asserts that "while additional material was provided when the provisional application was converted to the instant application, the provisional application was nonetheless adequate to enable the instant invention", however, on pages 5, 110-112 and 123 there is no mention of the marker D1S2681. This makes the record clear that the material was not present in the provisional application and is therefore new matter to the disclosure of the provisional. Thus, the criteria for 35 U.S.C. 112 compliance have not been met. Additionally, applicant asserts that page 5, line 21 of the provisional application disclose the identification of a region on human chromosome 1 located between 1q23 and 1q24 that contains a region associated with an increased risk of AH, however, applicant misapplies the disclosure since page 5 line 21 of the provisional application reads " screening methods currently

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available. Extensive blood tests and urinalysis that require". The above referenced pages does not disclose the marker and the above argument by the applicant is not persuasive, since the provisional application is absent essential matter as claimed in the present application and therefore lacks support. Furthermore, the provisional application does not provide a sequence listing and the SEQ ID NOs are blank (see for example, page 22, line 27 of the provisional application disclosure).

Therefore, the application remains non-compliant with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e).

7. The following new grounds of rejection are made based on the amendment:

Claim Rejections - Utility Rejections Under 35 USC § 101 And 35 USC 112, First Paragraph

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-8, 10-15 and 17 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility based on screening for increased risk of developing hypercalciuria by testing for mutation (s) at/in

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chromosome 1q23.3-1q24. The present application on page 5, refers to the invention as “relating to the discovery that there exists an area on human chromosome 1 that is genetically linked to absorptive hypercalciuria (AH), and thus to some forms of osteoporosis as well. However, no discussion is provided as to where the mutation demonstrates an increased risk for AH or what mutation was to have been detected. The disclosure simply states that the present invention involves a simple, straightforward genetic test that can be implemented in diagnosing SH and osteoporosis with hypercalciuria (see page 6) which indicates the gene involved in AH would need to be identified by refining the locus. Additionally, the disclosure also states that the genomic region associated with an increased risk of AH may have a sequence contained in at least one genetic sequence selected from the grouping provided in Claim 12.

The specification does not clearly set forth how a standardized screening method would be developed to screen for increased risk of AH. Applicant discloses that the genomic region associated with an increased risk of AH may localize to more than one gene in this area, and that it is expected that there are several unique mutations associated with an increased risk of AH in different individuals (see page 123). This much variability goes against the specification assertion that the invention provides a simple genetic test for increased risk of AH (see page 6). Furthermore, the specification on page 123 that AH is inherited in an autosomal dominant mode due to a gene mutation in the chromosome 1q23.3-q24 locus and that based on the map of chromosome 1 no genes of known function have been identified in this candidate region. Moreover, page 7 of the present specification indicates the genetic material of SEQ ID No. 1 is

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only putative and is not yet characterized whereas page 118 lines 5-10 of the application indicate an inherited defect is one likely cause of AH. The examples (1-7) do not demonstrate nor describe the claimed "...screening for increased risk...". In view of the foregoing, and absent data/evidence, the claimed invention lack utility. Since the specification sets forth no specific mutation, the claimed screening/detecting method lack a specific and substantial utility.

The assertion that a gene mutation in the chromosome 1q23.3-q24 is responsible for AH on page 123 of the specification and the claim made of a simple genetic test to screen for increased risk of AH followed by a discussion of the uncertainty of the gene region genes and variability of the mutation, may be indicia of a "real world" use, but in view of the absence of disclosure in the application of working examples (i.e., data) and complete details for carrying out the processes indicated in the claims, the utility indicated would require further experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-8, 10-15 and 17 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a

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well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite (and the dependent claims) because species (a) does not define what mutation is being detected. Furthermore, the claim is indefinite because it is unclear how species (b) relates to an increased risk. The claim is also indefinite because of the amendatory language "wherein said genomic region is comprised in chromosome 1q23.3-1q24." It is also not demonstrated where the mutation causes increased risk.

Claim 8 is indefinite for broadening Claim 7. Claim 1 already indicates it is on chromosome 1 by 1q23.3-1q24. Therefore, Claim 8 fails to further limit Claims 1 and 7.

Claims 10 and 11 are indefinite for depending from a canceled claim.

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
Amended Claim 12 is indefinite because on line 2 recites the word "the" twice. Furthermore, Claim 12 as amended is indefinite due to the multiplicity of periods "." in lines 3-5. See, e.g., "SEQ ID NO. 7", which should be "SEQ ID NO: 7".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS 

Patent Examiner



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